

HFA-305 Div. of Dockets
Mgt.

Approval Date: OCT 28 2004

FREEDOM OF INFORMATION SUMMARY
SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 140-897

REVALOR-S, REVALOR-IS, and REVALOR-G
Trenbolone Acetate and Estradiol

This supplement provides for addition to the labeling of the statements "A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal." to the warning section and "Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established." immediately following the indications.

Sponsored by:

Intervet, Inc.
29160 Intervet Lane
P.O. Box 318
Millsboro, DE 19966

FOIS 1

FREEDOM OF INFORMATION SUMMARY

REVALOR-S and REVALOR-IS
Ear Implant for Steers Fed in Confinement for Slaughter

REVALOR-G
Ear Implant for Pasture Cattle (Slaughter, Stocker, and Feeder Steers and Heifers)

1. GENERAL INFORMATION:

- a. File Number: NADA 140-897
- b. Sponsor: Intervet, Inc.
29160 Intervet Lane
P.O. Box 318
Millsboro, DE 19966
Drug Labeler Code: 057926
- c. Established Names: Trenbolone Acetate and Estradiol
- d. Propriety Names: REVALOR-S
REVALOR-IS
REVALOR-G
- e. Dosage Form: Implantation (ear implant) as per 21 CFR 522.2477

- f. How Supplied: REVALOR-S: Each shipping container contains 4 x 1000 dose packages. Each carton contains 10 x 100 dose packages. Each box contains 10 x 10 cartridge implants. Each cartridge contains 1 implant dose. Each dose consists of 120 mg trenbolone acetate and 24 mg estradiol.
- REVALOR-IS: Each shipping container contains 4 x 1000 dose packages. Each carton contains 10 x 100 dose packages. Each box contains 10 x 10 cartridge implants. Each cartridge contains 1 implant dose. Each dose consists of 80 mg trenbolone acetate and 16 mg estradiol.
- REVALOR-G: Each shipping container contains 4 x 1000 dose packages. Each carton contains 10 x 100 dose packages. Each box contains 10 x 10 cartridge implants. Each cartridge contains 1 implant dose. Each dose consists of 40 mg trenbolone acetate and 8 mg estradiol.
- g. How Dispensed: OTC
- h. Amount of Active Ingredients: REVALOR-S:
120 mg trenbolone acetate.
24 mg estradiol.
- REVALOR-IS:
80 mg trenbolone acetate.
16 mg estradiol.
- REVALOR-G:
40 mg trenbolone acetate.
8 mg estradiol.
- i. Route of Administration: Subcutaneous implantation on the posterior aspect of the middle one-third of the ear by means of an implant gun.
- j. Species/Class: REVALOR-S and REVALOR-IS: Steers fed in confinement for slaughter.
- REVALOR-G: Pasture cattle (slaughter, stocker, and feeder steers and heifers).

No new target animal safety data are required for the approval of this supplement. The products' target animal safety has been established in the Freedom of Information (FOI) Summaries for the parent new animal drug application for REVALOR-S, REVALOR-IS, and REVALOR-G (NADA 140897).

4. HUMAN SAFETY:

No new human food safety data are required for the approval of this supplement. The products' human food safety has been established in the Freedom of Information (FOI) Summaries for the parent new animal drug application for REVALOR-S, REVALOR-IS, and REVALOR-G (NADA 140897).

5. AGENCY CONCLUSIONS:

The information submitted in support of this NADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations providing for the addition to the labeling of the statements "A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal." to the warning section and "Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established." immediately following the indications. The labeling is modified to conform to agency policy (69 FR 135 pages 42443-42444 dated July 15, 2004, and 69 FR 68 page 18594 dated April 8, 2004.)

The Center for Veterinary Medicine has concluded that, for these products, adequate directions for use by the layperson have been provided and the products will have over-the-counter (OTC) status. Label directions are accompanied by pictorial diagrams and detailed instruction in plain language. The drugs are not controlled substances. The products' status remains OTC. The labeling is adequate for the intended use and has sufficient warnings/statements to prevent illegal use in veal calves.

This approval does not qualify for marketing exclusivity under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act.

Under the Center's supplemental approval policy (21 CFR 514.106(b)(2)), this is a Category II change. The approval of this change is not expected to have any adverse effect on the safety or effectiveness of this new animal drug. Accordingly, this approval did not require a reevaluation of the safety and effectiveness data in the parent application.

No patent information was submitted by the sponsor with this application.

6. ATTACHMENTS:

Facsimile Labeling is attached as indicated below:

REVALOR-S Package Insert
REVALOR-S Box Label
REVALOR-S Carton Label
REVALOR-S Shipping Container Label
REVALOR-IS Package Insert
REVALOR-IS Box Label
REVALOR-IS Carton Label
REVALOR-IS Shipping Container Label
REVALOR-G Package Insert
REVALOR-G Box Label
REVALOR-G Carton Label
REVALOR-G Shipping Container Label



Revalor®-S

(trenbolone acetate
and estradiol)

WARNING

Not to be used in animals intended for subsequent breeding, or in dairy animals. For Animal Treatment Only. Not for Use in Humans. Implant pellets in the ear only. Any other location is in violation of Federal Law. Do not attempt salvage of implanted site for human or animal food.

A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

STORAGE CONDITIONS

Store in a refrigerator (2-8° C; 36-47° F) and protect from sunlight. Use before the expiration date printed on the box and on the cartridge.

PACKAGE QUANTITIES

Box of 10 x 10 cartridge implants.

Made in Austria by:
Intervet GesmbH

Distributed by:
Intervet Inc.
Millsboro, DE 19966

780900-C



NADA # 140-897, Approved by FDA

FOR STEERS FED IN CONFINEMENT FOR SLAUGHTER

DESCRIPTION

Revalor®-S (trenbolone acetate and estradiol) is an implant containing 120 mg of trenbolone acetate and 24 mg estradiol. Each implant consists of 8 small yellow pellets. Ten implants are provided in a cartridge. Manufactured by a non-sterilizing process.

INDICATIONS

Increases rate of weight gain and improves feed efficiency in a slow-release delivery system.
Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established.

NOTE

Studies have demonstrated that the administration of Revalor®-S can result in decreased marbling scores when compared to non-implanted steers.

DOSAGE

Dosage Form:

One implant containing 120 mg trenbolone acetate and 24 mg estradiol is administered to each animal. The 8 pellets which make up the dosage of Revalor®-S are contained in one division of the multiple dose cartridge. Ten doses are in each cartridge. The cartridge is designed to be used with a special implant gun.

Route of Administration:

The implant is placed under the skin on the posterior aspect of the ear by means of a special implanter available from Intervet Inc.



With the animal suitably restrained, the skin on the outer surface of the ear should be cleaned. The implant is then administered by the method shown in the diagram below.

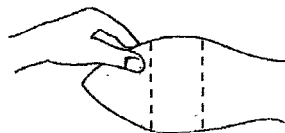


Fig. 1 - Ear of Bovine Ready for Implantation

SITE OF IMPLANTATION

After appropriately restraining the animal to allow access to the ear, cleanse the skin at the implant needle puncture site. It is subcutaneous between the skin and cartilage on the back side of the ear and below the midline of the ear. The implant must not be placed closer to the head than the edge of the cartilage ring farthest from the head. The location of insertion of the needle is a point toward the tip of the ear and at least a needle length away from the intended deposition site. Care should be taken to avoid injuring the major blood vessels or cartilage of the ear.

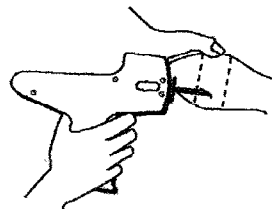
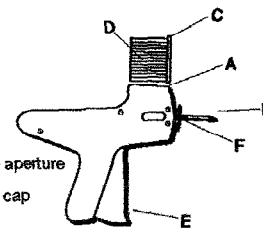


Fig. 2 - Rear view of the bovine ear showing the Site for Insertion of the Implanter Needle.

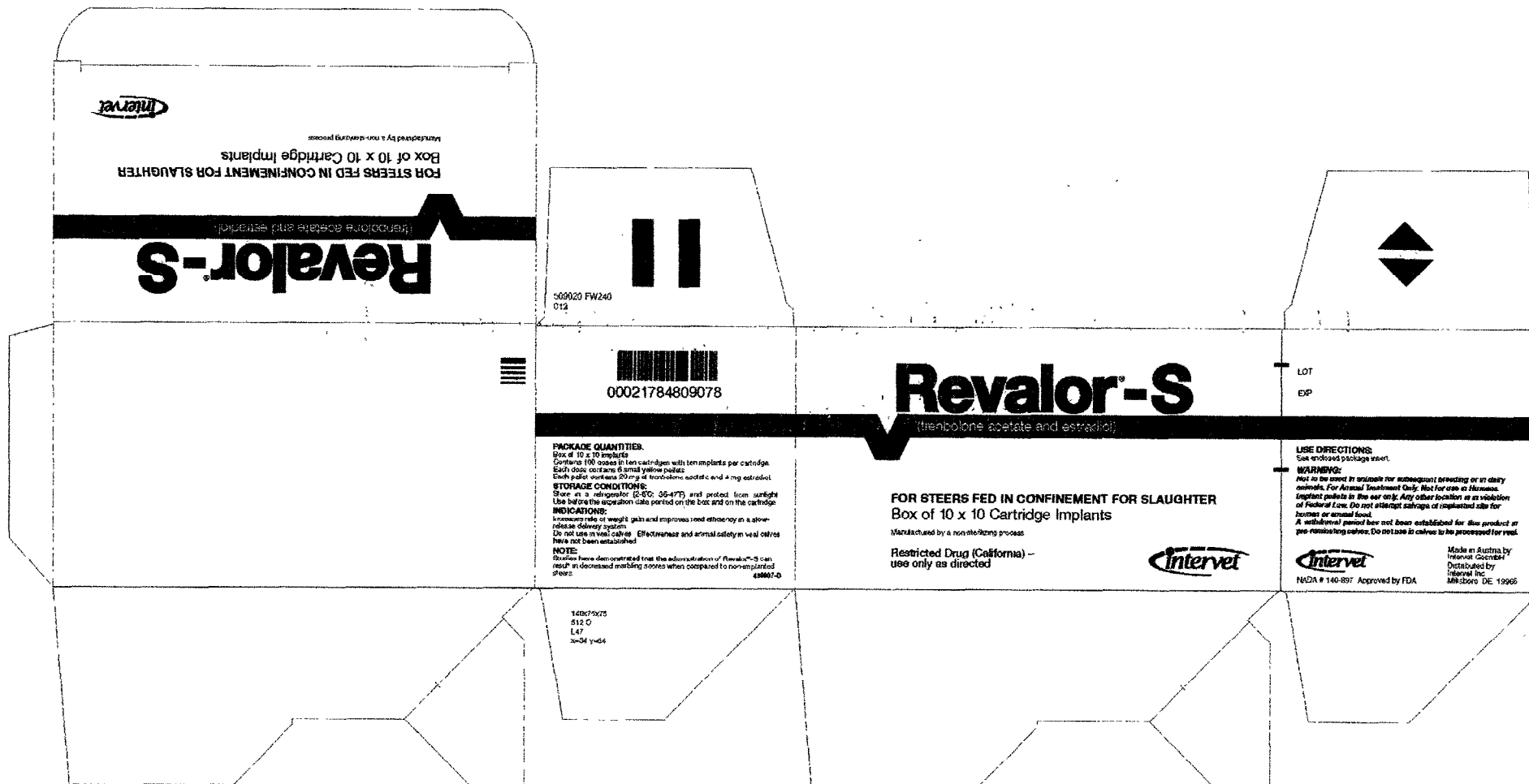
METHOD OF USE

1. Do not remove the cap of the cartridge containing the implants.
2. Place the cartridge (D) with the capped end to the front into slot at the top of the implanter magazine marked (A) on the diagram.
3. Gently push the cartridge into the slot until it clicks into place.
4. The implanter is then ready for use.
5. Take the ear of the animal firmly with the free hand in the manner shown in Fig. 1. Then insert the needle into the subcutaneous tissue at the point indicated in Fig. 2.
6. After inserting the needle to its full extent, squeeze the trigger (E) gradually. Allow the pellets of the implant to be deposited in a single row.
7. Withdraw the implanter. This will advance the cartridge one groove in the magazine and the next implant is now ready for use.
8. When all the implants have been administered, the cartridge will discharge out the bottom of the magazine and may be replaced by a new one.
9. To change the needle, loosen the needle locking nut labeled (F) in Fig. 3 and replace the needle. Tighten the nut finger tight and the implanter is ready for use.



- A - Magazine aperture
- B - Needle
- C - Cartridge cap
- D - Cartridge
- E - Trigger
- F - Needle locking nut

Fig. 3 - Diagram of the Implanter and Cartridge



Revalor-S



50021784809073

(trenbolone acetate and estradiol)

FOR STEERS FED IN CONFINEMENT FOR SLAUGHTER

NET CONTENTS

Box of 10 x 100 dose packages

Manufactured by a non-sterilizing process

STORAGE CONDITIONS:

Store in a refrigerator (2-8° C; 36-47° F) and protect from sunlight.
Use before the expiration date printed below and on the cartridge.

WARNING:

Not to be used in animals intended for subsequent breeding, or in dairy animals.
For Animal Treatment Only. Not for Use in Humans. Implant pellets in the ear
only. Any other location is in violation of Federal Law. Do not attempt salvage of
implanted site for human or animal food.
A withdrawal period has not been established for this product in pre-ruminating
calves. Do not use in calves to be processed for veal.

780907-C

509017 CW240 011

Intervet

Made in Austria by:
Intervet GesmbH
Distributed by:
Intervet Inc.
Millsboro, DE 19966

LOT
EXP

Intervet

NADA # 140-697 Approved by FDA

Revalor-S



30021784809079

(trenbolone acetate and estradiol)

FOR STEERS FED IN CONFINEMENT FOR SLAUGHTER

NET CONTENTS

4 x 1000 dose packages

Manufactured by a non-sterilizing process

STORAGE CONDITIONS:

Store in a refrigerator (2-8° C, 36-47° F) and protect from sunlight.
Use before the expiration date printed below and on the cartridge

WARNING:

Not to be used in animals intended for subsequent brooding, or in dairy animals.
For Animal Treatment Only. Not for Use in Humans. Implant pellets in the ear
only. Any other location is in violation of Federal Law. Do not attempt salvage of
implanted site for human or animal food.
A withdrawal period has not been established for this product in pre-ruminating
calves. Do not use in calves to be processed for veal.

780908-C

509018 ZW240 011

Intervet

Made in Austria by:
Intervet GmbH

Distributed by:
Intervet Inc.
Millsboro, DE 19966

LOT
EXP

Intervet

NADA # 140-887. Approved by FDA



Revalor®-IS

(trenbolone acetate
and estradiol)

WARNING

Not to be used in animals intended for subsequent breeding, or in dairy animals. For Animal Treatment Only. Not for Use in Humans. Implant pellets in the ear only. Any other location is in violation of Federal Law. Do not attempt salvage of implanted site for human or animal food.

A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

STORAGE CONDITIONS

Store in a refrigerator (2-8° C; 36-47° F) and protect from sunlight. Use before the expiration date printed on the box and on the cartridge.

PACKAGE QUANTITIES

Box of 10 x 10 cartridge implants.

Made in Austria by:
Intervet GmbH

Distributed by:
Intervet Inc.
Millsboro, DE 19966

482020-C



NADA # 140-897, Approved by FDA

FOR STEERS FED IN CONFINEMENT FOR SLAUGHTER

DESCRIPTION

Revalor®-IS (trenbolone acetate and estradiol) is an implant containing 80 mg of trenbolone acetate and 16 mg estradiol. Each implant consists of 4 small yellow pellets. Ten implants are provided in a cartridge.

Manufactured by a non-sterilizing process.

INDICATIONS

Increases rate of weight gain and improves feed efficiency in a slow-release delivery system.

Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established.

DOSAGE

Dosage Form:

One implant containing 80 mg trenbolone acetate and 16 mg estradiol is administered to each animal. The 4 pellets which make up the dosage of Revalor®-IS are contained in one division of the multiple dose cartridge. Ten doses are in each cartridge. The cartridge is designed to be used with a special implant gun.

Route of Administration:

The implant is placed under the skin on the posterior aspect of the ear by means of a special implanter available from Intervet Inc.



With the animal suitably restrained, the skin on the outer surface of the ear should be cleaned. The implant is then administered by the method shown in the diagram below.

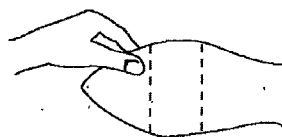


Fig. 1 - Ear of Bovine Ready for Implantation

SITE OF IMPLANTATION

After appropriately restraining the animal to allow access to the ear, cleanse the skin at the implant needle puncture site. It is subcutaneous between the skin and cartilage on the back side of the ear and below the midline of the ear. The implant must not be placed closer to the head than the edge of the cartilage ring farthest from the head. The location of insertion of the needle is a point toward the tip of the ear and at least a needle length away from the intended deposition site. Care should be taken to avoid injuring the major blood vessels or cartilage of the ear.

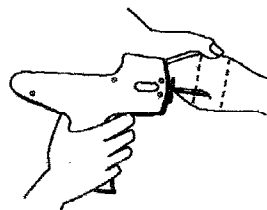
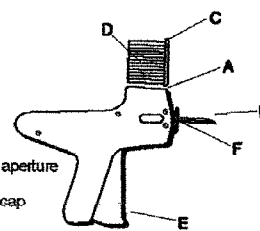


Fig. 2 - Rear View of the Bovine Ear Showing the Site for Insertion of the Implanter Needle.

METHOD OF USE

1. Do not remove the cap of the cartridge containing the implants.
2. Place the cartridge (D) with the capped end to the front into slot at the top of the implanter magazine marked (A) on the diagram.
3. Gently push the cartridge into the slot until it clicks into place.
4. The implanter is then ready for use.
5. Take the ear of the animal firmly with the free hand in the manner shown in Fig. 1. Then insert the needle into the subcutaneous tissue at the point indicated in Fig. 2.
6. After inserting the needle to its full extent, squeeze the trigger (E) gradually. Allow the pellets of the implant to be deposited in a single row.
7. Withdraw the implanter. This will advance the cartridge one groove in the magazine and the next implant is now ready for use.
8. When all the implants have been administered, the cartridge will discharge out the bottom of the magazine and may be replaced by a new one.
9. To change the needle, loosen the needle locking nut labeled (F) in Fig. 3 and replace the needle. Tighten the nut finger tight and the implanter is ready for use.



- A - Magazine aperture
- B - Needle
- C - Cartridge cap
- D - Cartridge
- E - Trigger
- F - Needle locking nut

Fig. 3 - Diagram of the Implanter and Cartridge

Intervet

FOR STEERS FED IN CONFINEMENT FOR SLAUGHTER
Box of 10 x 10 Cartridge Implants

Manufactured by a non-drinking process

Revalor-IS
(trenbolone acetate and estradiol)

509016 PM240
012



00021784813006

PACKAGE QUANTITIES:

Box of 10 x 10 implants
Contains 100 doses in an cartridge with ten implants per cartridge
Each dose contains 4 small yellow pellets
Each pellet contains 20 mg of trenbolone acetate and 4 mg estradiol
STORAGE CONDITIONS:
Store in a refrigerator (2-8°C, 36-47°F) and protect from sunlight
Use before the expiration date printed on the box and on the cartridge.
INDICATIONS:
Increases rate of weight gain and improves feed efficiency in a slow-
release delivery system.
Do not use in real calves. Effectiveness and animal safety in real calves
have not been established.
USE DIRECTION:
See enclosed package insert

AN100-D

140275275
021C
140
x=29 y=60

Revalor-IS

(trenbolone acetate and estradiol)

FOR STEERS FED IN CONFINEMENT FOR SLAUGHTER
Box of 10 x 10 Cartridge Implants

Manufactured by a non-drinking process

Restricted Drug (California) -
use only as directed.

Intervet

LOT
EXP

WARNING:

Not to be used in animals for subsequent breeding or in dairy
animals. For Animal Treatment Only. Not for use in Humans.
Inject pellets in the ear only. Any other location is in violation of
Federal Law. Do not attempt surgery of implanted site for human
or animal food.
A withdrawal period has not been established for this product in
pre-slaughtering calves. Do not use in calves to be processed for veal.

Intervet

NADA # 140-897 Approved by FDA

Made in Austria by
Harnett GmbH
Distributed by
Intervet Inc.
Millsboro DE 19966

Revalor[®]-IS



50021784813001

(trenbolone acetate and estradiol)

FOR STEERS FED IN CONFINEMENT FOR SLAUGHTER

NET CONTENTS

Box of 10 x 100 dose packages

Manufactured by a non-sterilizing process

STORAGE CONDITIONS:

Store in a refrigerator (2-8° C; 36-47° F) and protect from sunlight.
Use before the expiration date printed below and on the cartridge

WARNING:

Not to be used in animals intended for subsequent breeding, or in dairy animals.
For Animal Treatment Only. Not for Use in Humans. Implant pellets in the ear
only. Any other location is in violation of Federal Law. Do not attempt salvage of
implanted site for human or animal food.

A withdrawal period has not been established for this product in pre-ruminating
calves. Do not use in calves to be processed for veal.

481330-C

509013 CW240 011

Intervet

Made in Austria by:
Intervet GeomBH
Distributed by:
Intervet Inc.
Millsboro, DE 19966

LOT
EXP

Intervet

NADA # 140-897, Approved by FDA

Revalor-[®]IS

(trenbolone acetate and estradiol)



30021784813007



N

FOR STEERS FED IN CONFINEMENT FOR SLAUGHTER

NET CONTENTS

4 x 1000 dose packages

Manufactured by a non-sterilizing process

STORAGE CONDITIONS:

Store in a refrigerator (2-8° C; 36-47° F) and protect from sunlight.

Use before the expiration date printed below and on the cartridge

WARNING:

Not to be used in animals intended for subsequent breeding, or in dairy animals. For Animal Treatment Only. Not for Use in Humans. Implant pellets in the ear only. Any other location is in violation of Federal Law. Do not attempt salvage of implanted site for human or animal food.

A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

781300-C

509014 ZW240 011



Made in Austria by:
Intervet GeomBH
Distributed by:
Intervet Inc.
Millsboro, DE 19966

LOT
EXP



NADA # 140-897, Approved by FDA



Revalor®-G

(trenbolone acetate
and estradiol)

WARNING

Not to be used in animals intended for subsequent breeding, or in dairy animals. For Animal Treatment Only. Not for Use in Humans. Implant pellets in the ear only. Any other location is in violation of Federal Law. Do not attempt salvage of implanted site for human or animal food.

A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

STORAGE CONDITIONS

Store in a refrigerator (2-8° C; 36-47° F) and protect from sunlight. Use before the expiration date printed on the box and on the cartridge.

PACKAGE QUANTITIES

Box of 10 x 10 cartridge implants.

Made in Austria by:
Intervet GesmbH

Distributed by:
Intervet Inc.
Millsboro, DE 19966

781200-C



NADA # 140-897, Approved by FDA

FOR PASTURE CATTLE (SLAUGHTER, STOCKER AND FEEDER STEERS AND HEIFERS)

DESCRIPTION

Revalor®-G is an implant containing 40 mg of trenbolone acetate and 8 mg estradiol. Each implant consists of 2 small yellow pellets. Ten implants are provided in a cartridge.

INDICATIONS

Increases rate of weight gain in pasture cattle (slaughter, stocker, and feeder steers and heifers) in a slow-release delivery system.

Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established.

DOSAGE

Dosage Form:

One implant containing 40 mg trenbolone acetate and 8 mg estradiol is administered to each animal. The 2 pellets which make up the dosage of Revalor®-G are contained in one division of the multiple dose cartridge. Ten doses are in each cartridge. The cartridge is designed to be used with a special implant gun.

Route of Administration:

The implant is placed under the skin on the posterior aspect of the ear by means of a special implanter available from Intervet Inc.



With the animal suitably restrained, the skin on the outer surface of the ear should be cleaned. The implant is then administered by the method shown in the diagram below.

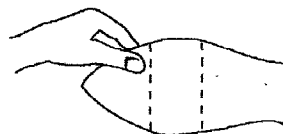


Fig. 1 - Ear of Bovine Ready for Implantation

SITE OF IMPLANTATION

After appropriately restraining the animal to allow access to the ear, cleanse the skin at the implant needle puncture site. It is subcutaneous between the skin and cartilage on the back side of the ear and below the midline of the ear. The implant must not be placed closer to the head than the edge of the cartilage ring farthest from the head. The location of insertion of the needle is a point toward the tip of the ear and at least a needle length away from the intended deposition site. Care should be taken to avoid injuring the major blood vessels or cartilage of the ear.

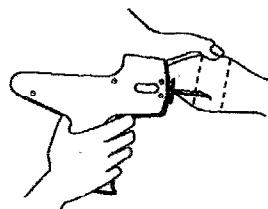


Fig. 2 - Rear View of the Bovine Ear Showing the Site for Insertion of the Implant Needle.

METHOD OF USE

1. Do not remove the cap of the cartridge containing the implants.
2. Place the cartridge (D) with the capped end to the front into slot at the top of the implanter magazine marked (A) on the diagram.
3. Gently push the cartridge into the slot until it clicks into place.
4. The implanter is then ready for use.
5. Take the ear of the animal firmly with the free hand in the manner shown in Fig. 1. Then insert the needle into the subcutaneous tissue at the point indicated in Fig. 2.
6. After inserting the needle to its full extent, squeeze the trigger (E) gradually. Allow the pellets of the implant to be deposited in a single row.
7. Withdraw the implanter. This will advance the cartridge one groove in the magazine and the next implant is now ready for use.
8. When all the implants have been administered, the cartridge will discharge out the bottom of the magazine and may be replaced by a new one.
9. To change the needle, loosen the needle locking nut labeled (F) in Fig. 3 and replace the needle. Tighten the nut finger tight and the implanter is ready for use.

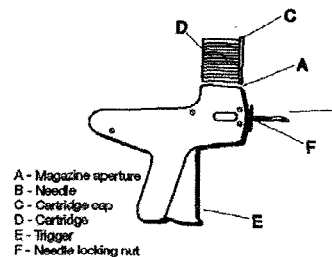


Fig. 3 - Diagram of the Implanter and Cartridge



Manufactured by a non-sterile process
Box of 10 x 10 Cartridge Implants
(SLAUGHTER, STOCKER AND FEEDER STEERS AND HEIFERS)

Revalor-G
(trenbolone acetate and estradiol)



509034 PW240
C12



00021784811002

Revalor-G
(trenbolone acetate and estradiol)

LOT
EXP

PACKAGE QUANTITIES:
Box of 10 x 10 implants
Contains 100 doses in ten cartridges with ten implants per cartridge.
Each dose contains 2 small yellow pellets.
Each pellet contains 20 mg of trenbolone acetate and 4 mg estradiol.

STORAGE CONDITIONS:
Store in a refrigerator (2-8°C, 36-47°F) and protect from sunlight.
Use before the expiration date printed on the box and on the cartridge.

INDICATIONS:
Increases rate of weight gain in a slow-release delivery system.
Do not use in veal calves. Embryonated and adult calves in veal calves have not been established.

USE DIRECTIONS:
See enclosed package insert

49709-0

140x75x5
350C
L250
X=GR; Y=BL

FOR PASTURE CATTLE
(SLAUGHTER, STOCKER AND FEEDER STEERS AND HEIFERS)
Box of 10 x 10 Cartridge Implants

Manufactured by a non-sterile process

Restricted Drug (California) –
use only as directed.



WARNING:

Not to be used in animals for subsequent breeding or in dairy animals. For Animal Treatment Only. Not for use in humans. Implant pellets in the ear only. Any other location is in violation of Federal Law. Do not attempt salvage of implanted sites for human or animal food.

A withdrawal period has not been established for this product in pre-existing calves. Do not use in calves to be processed for veal.



NADA # 140-397, Approved by FDA

Made in Austria by
Intervet Geestlich
Distributed by
Intervet Inc.
Millsboro, DE 19965

Revalor-G

50 021784 81100 7

(mestrolone acetate and estradiol)

FOR PASTURE CATTLE

(SLAUGHTER, STOCKER AND FEEDER STEERS AND HEIFERS)

NET CONTENTS

Box of 10 x 100 dose packages

Manufactured by a non-sterilizing process

STORAGE CONDITIONS:

Store in a refrigerator (2-8° C; 36-47° F) and protect from sunlight.
Use before the expiration date printed below and on the cartridge

WARNING:

Not to be used in animals intended for subsequent breeding, or in dairy animals.
For Animal Treatment Only. Not for Use in Humans. Implant pellets in the ear
only. Any other location is in violation of Federal Law. Do not attempt salvage of
implanted site for human or animal food.

A withdrawal period has not been established for this product in pre-ruminating
calves. Do not use in calves to be processed for veal.

781207-C

509001 CW240 011

Intervet

Made in Austria by:
Intervet GeembH
Distributed by:
Intervet Inc.
Millsboro, DE 19966

LOT
EXP

Intervet

NADA # 140-887, Approved by FDA

Revalor-G

30 0 21784 81100 3

(trenbolone acetate and estradiol)

FOR PASTURE CATTLE
(SLAUGHTER, STOCKER AND FEEDER STEERS AND HEIFERS)

NET CONTENTS

4 x 1000 dose packages

Manufactured by a non-sterilizing process

STORAGE CONDITIONS:

Store in a refrigerator (2-8° C; 36-47° F) and protect from sunlight.

Use before the expiration date printed below and on the cartridge

WARNING:

Not to be used in animals intended for subsequent breeding, or in dairy animals.
For Animal Treatment Only. Not for Use in Humans. Implant pellets in the ear
only. Any other location is in violation of Federal Law. Do not attempt salvage of
implanted gils for human or animal food.

A withdrawal period has not been established for this product in pre-ruminating
calves. Do not use in calves to be processed for veal.

781208-C 509002 ZW240 011

Intervet

Made in Austria by:
Intervet GesmbH
Distributed by:
Intervet Inc.
Millsboro, DE 19966

LOT
EXP

Intervet

NADA # 140-897, Approved by FDA